NDA 20589/S-039

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
Attention: Alberto J. Garzon
Regulatory Affairs Sr. Manager
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Mr. Garzon:

Please refer to your supplemental new drug application (sNDA) dated and received on May 20, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Advil (ibuprofen) oral suspension, 100 mg/ 5 mL.

This Prior Approval supplemental new drug application provides for the following changes:

- Qualification of an alternate drug product manufacturing site (b) (4) for all six flavors.
- Changes that include relaxations and deletions of acceptable criteria of the in-process control, excipient specification and release & shelf-life specification of the finished product.
- Updated labeling to account for the change in the Tamper Evidence statement and the artwork drawings used by the alternate manufacturer.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL) as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling, described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
Children's Advil 4 fl. oz. outer container (carton-bilingual label) (Fruit flavor)	July 19, 2022

Children's Advil 4 fl. oz. outer container (carton-piggyback bilingual label) (Fruit flavor)	May 20, 2022
Children's Advil 4 fl. oz. immediate container (bottle-bilingual label) (Fruit flavor)	May 20, 2022
Children's Advil 4 fl. oz outer container (carton) (Grape flavor)	July 19, 2022
Children's Advil 4 fl. oz. immediate container (bottle) (Grape flavor)	May 20, 2022
Children's Advil 4 fl. oz. outer container (carton) (White Grape flavor)	July 19, 2022
Children's Advil 4 fl. oz. immediate container (bottle) (White Grape flavor)	May 20, 2022
Children's Advil 4 fl. oz. outer container (carton) (Bubble gum flavor)	July 19, 2022
Children's Advil 4 fl. oz. immediate container (bottle) (Bubble gum flavor)	May 20, 2022
Children's Advil 4 fl. oz. outer container (carton) (Sugar-free Dye-free Berry flavor)	July 19, 2022
Children's Advil 4 fl. oz. immediate container (bottle) (Sugar-free Dye-free Berry flavor)	May 20, 2022
Children's Advil 4 fl. oz. outer container (carton) (Dye-free Blue Raspberry flavor)	July 19, 2022
Children's Advil 4 fl. oz. immediate container (bottle) (Dye-free Blue Raspberry flavor)	May 20, 2022

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20589/S-039**." Approval of this submission by FDA is not required before the labeling is used.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call LCDR Sally Doan, Regulatory Project Manager, at (301) 796-8025.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container Labeling

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
09/20/2022 09:12:00 AM